

Date of Decision Notification: 16 Jul 2020

Dear Professor Wiggers

2019/ETH00998: Effectiveness of a practice change intervention to increase the provision of recommended antenatal care regarding maternal alcohol use during pregnancy.

The Amendment has been reviewed by the Executive Officer as delegated by the Hunter New England Human Research Ethics Committee and has been approved for the following:

- Addition of Brianna Fjeldsoe and Nayerra Hudson to the research team
- Women's Antenatal Survey sample to be extended within the approved Hunter New England Local Health District to include two additional sectors - Tablelands Sector (Armidale, Inverell, Glen Innes); and Hunter Valley Sector (Singleton, Muswellbrook, Scone)
- Women from the currently approved survey sites to also be surveyed until sufficient numbers are reached to enable an assessment of the effectiveness of the behaviour change intervention at each site - Mehi Sector (Narrabri and Moree); Lower Hunter Sector (Maitland); Greater Newcastle Sector (Belmont and John Hunter Hospitals); Lower Mid North Coast Sector (Taree/Manning); Peel Sector (Tamworth, Quirindi, Gunnedah)
- Addition of another time point for sampling women who attend antenatal care at John Hunter Hospital's Maternity Service, between 12-14 weeks gestational age
- Sampling methodology modified to sample all women from smaller sites/regional sectors to over-sample Aboriginal women, remaining sample to be made up of a random sample from the Greater Newcastle Sector (John Hunter Hospital Maternity Services)
- Changes to Aboriginal and AMIHS Focus Groups

The following documentation is included in this approval:

- **Focus Group Information Statement** (Version 3 dated 16 July 2020)
- **Focus Group Consent Form** (Version 3 dated 7 July 2020)
- **Focus Group Question Guide** (Version 3 dated 7 July 2020)
- **Postnatal Women's Information Statement** (Version 4 dated 16 July 2020)
- **Postnatal Interview Guide** (Version 1 dated 7 July 2020)
- **Women's Antenatal Alcohol Initiative Script** (Version 10 dated 7 July 2020)

It is noted that the Hunter New England Human Research Ethics Committee is constituted in accordance with the National Statement on Human Conduct in Research, 2007 (NHMRC). This decision will be ratified at the next meeting of the Committee to be held

on 19 August 2020.

This email constitutes ethical and scientific approval only.

Please Note: This is your approval, you will no longer receive a formal letter.

Please contact us if you would like to discuss any aspects of this process further, at HNELHD-HREC@health.nsw.gov.au.

Kind regards

Debbie Madden

Ethics Administration Officer

Research Office

Hunter New England Local Health District

Ph: 02 49855929

Email: Debbie.madden@health.nsw.gov.au